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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/622,373	07/18/2003	Jennifer L. Whistler	316E-001510US	4987

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EXAMINER	
BRANNOCK, MICHAEL T	

ART UNIT	PAPER NUMBER
1649	

DATE MAILED: 06/19/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/622,373	WHISTLER ET AL.	
	Examiner	Art Unit	
	Michael Brannock	1649	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *10 August 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-78* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-78* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-12, 14, 15, 17-26, 28, 29, as the claims relate to in vitro methods, drawn to in vitro methods of inhibiting or enhancing agonist induced down regulation of a GPCR, classification dependent on the chemical identity of the inhibitor/enhancer and/or the physical nature of the practice of the method, e.g. mode of administration and detection.

II. Claims 1-11, 13, 14, 16, 17-25, 27-29, as the claims relate to in vivo methods, drawn to in vivo methods of inhibiting or enhancing agonist induced down regulation of a GPCR, classification dependent on the chemical identity of the inhibitor/enhancer, and/or the physical nature of the construction of the method, e.g. method of administration.

III. Claims 30-42, 53, 54, 55, as the claims are drawn to a GASP polypeptide, drawn to GASP polypeptides, classified in class 530, subclass 350.

IV. Claims 43-46, 53, 54, drawn to GPCR polypeptides, classified in class 530, subclass 350.

V. Claims 47-55, as the claims relate to GASP, drawn to GASP encoding polynucleotides, host cells, vectors and methods of producing a GASP polypeptide, classified in class 536, subclass 23.5.

VI. Claims 47-55, as the claims relate to a GPCR, drawn to GPCR encoding polynucleotides, host cells and methods of producing a GPCR polypeptide, classified in class 536, subclass 23.5.

VII. Claims 56 and 57, as the claims relate to a GASP polypeptide, drawn to antibodies that bind a GASP polypeptide, classified in class 530, subclass 388.22.

VIII. Claims 56 and 57, as the claims relate to a GPCR polypeptide, drawn to antibodies that bind a GPCR polypeptide, classified in class 530, subclass 388.22.

IX. Claims 58-61, 63-70, 72-78, as the claims relate to the binding of a polypeptide, drawn to methods for screening for an agent that modulates agonist induced down regulation of a GPCR by detecting the binding of the agent to a polypeptide or the increase or decrease in the amount of a polypeptide, classified in class 436, subclass 501.

IX. Claims 58, 59, 62, 68, 69, 71-78, as the claims relate to the binding of a polynucleotide, drawn to methods for screening for an agent that modulates agonist induced down regulation of a GPCR by detecting the binding of the agent to the polynucleotide or detecting an increase or decrease in the amount of a polynucleotide, classified in class 435, subclass 6.

The inventions are distinct, each from the other because of the following reasons:

Although there are no provisions under the section for "Relationship of Inventions" in M.P.E.P. § 806.05 for inventive groups that are directed to different methods, restriction is deemed to be proper because these methods appear to constitute patentably distinct inventions for the following reasons: Groups I, II, IX and X are directed to methods that are distinct both

physically and functionally, and are not required one for the other. Group I requires in vitro methods of using a compound that inhibits agonist induced down regulation of a GPCR, which is not required by any of the other groups. Group II requires in vivo methods of using a compound that inhibits agonist induced down regulation of a GPCR, which is not required by any of the other groups. Additionally it does not appear that one would need to be in possession of the compounds of Groups I or II in order to practice the inventions of Groups IX or X. Group IX requires detecting the binding of an agent to a polypeptide or the increase or decrease in the amount of a polypeptide, which is not required by any of the other groups. Group X requires detecting binding of an agent to a polynucleotide or detecting an increase or decrease in the amount of a polynucleotide, which is not required of any of the other groups.

Although there are no provisions under the section for "Relationship of Inventions" in M.P.E.P. § 806.05 for inventive groups that are directed to different products, restriction is deemed to be proper because these methods appear to constitute patentably distinct inventions for the following reasons: Groups III -VIII are directed to products that are distinct both physically and functionally, and are not required one for the other, and are therefore patentably distinct. Further, the protein of Group III and IV can be prepared by processes which are materially different from recombinant DNA expression of Group V and VI, respectively, such as by chemical synthesis, or by isolation and purification from natural sources. Additionally, the DNA of Groups V and VI can be used other than to make the protein of Groups III and IV, such in gene therapy or as a probe in nucleic acid hybridization assays. The protein of Groups III and IV can be used in materially different methods other than to make the antibodies of Group VII and VIII, respectively, such as in therapeutic or diagnostic methods (e.g., in screening).

Additionally, although the antibodies of Groups VII and VIII can be used to obtain the DNA of Groups V and VI, they can also be used in materially different methods, such as in various diagnostic (e.g., in as a probe in immunoassays or immunochromatography), or therapeutic methods.

The inventions of Groups III, V, and VII, which relate specifically to GASP are directed to products and methods that are patentably distinct from those of Groups IV, VI, and VIII, which specifically relate to GPCRs. These two groups of inventions are considered to be distinct from each other because neither of which is required for the manufacture or use of the other. The polypeptides of Group III and IV are distinct from each other; although they interact with each other in vivo and in vitro, each is capable of separate uses, for example as distinct diagnostic agents or for the production of patentably distinct antibodies of Groups VII and VIII each of which are themselves not physically or functionally related to each other in terms of the antigen to which they bind. Likewise the polynucleotides of Groups V and VI are distinct from each other because they are structurally and functionally unrelated, one not being required for the use or manufacture of the other.

The polypeptides of Groups III and IV are related to the methods of Groups I, II, IX, and X as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the polypeptides of Groups III and IV are patentably distinct from each of the methods of Groups I, II, IX, and X because the polypeptides can be used in ways that are materially and functionally

different than each of the methods because, as discussed above, each of the methods of Groups I, II, IX, and X are materially and functionally distinct from each other.

The polynucleotides of Groups V and VI are related to the methods of Groups I, II, IX, and X as product and process of use. In the instant case the polynucleotides of Group V and VI are patentably distinct from each of the methods of Groups I, II, IX, and X because the polynucleotides can be used in ways that are materially and functionally different than each of the methods because, as discussed above, each of the methods of Groups I, II, IX, and X are materially and functionally distinct from the others.

The antibodies of Groups VII and VIII are related to the methods of Groups I, II, IX, and X as product and process of use. In the instant case the antibodies of Group VII and VIII are patentably distinct from each of the methods of Groups I, II, IX, and X because the can be used in ways that are materially and functionally different than each of the methods because, as discussed above, each of the methods of Groups I, II, IX, and X are materially and functionally distinct from the others.

Therefore, because these inventions are distinct for the reasons given above and because a search and examination of all the groups in one patent application would result in an undue burden, since the searches for the groups are not co-extensive, the classification is different, and the subject matter is divergent, restriction for examination purposes as indicated is proper.

Claims 1-78 are generic to a plurality of disclosed patentably distinct species comprising polypeptides of SEQ ID NO: 2 and 6, and polynucleotides encoding same. Each polypeptide and each polynucleotide are distinct and divergent molecules, the use of one not being required for the of any other. Furthermore, a search of one could not be relied upon, solely, to provide art

that is anticipatory or that might render obvious any other, and to search more than one species in a single application would be unduly burdensome. Applicant is required under 35 U.S.C. 121 to elect a single disclosed species, even though this requirement is traversed.

Claims 1-29, 34, 35, 37-78 are generic to a plurality of disclosed patentably distinct species comprising specific GPCRs, e.g., delta opioid receptor, kappa opioid receptor, D2 dopamine receptor, etc. and polynucleotides encoding same. Each polypeptide and each polynucleotide are distinct and divergent molecules, the use of one not being required for the of any other. Furthermore, a search of one could not be relied upon, solely, to provide art that is anticipatory or that might render obvious any other, and to search more than one species in a single application would be unduly burdensome. Applicant is required under 35 U.S.C. 121 to elect a single disclosed species, even though this requirement is traversed.

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143). Applicant is advised that a reply to this requirement must include an identification of each of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai, In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to

retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.**

Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01

Conclusion

The Art Unit location of your application in the USPTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Art Unit 1649.Please note the new central fax number for official correspondence below:

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Brannock, Ph.D., whose telephone number is (571) 272-0869. The examiner can normally be reached on Mondays through Fridays from 10:00 a.m. to 4:00 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Janet Andres, Ph.D., can be reached at (571) 272-0867. Official papers filed by fax should be directed to **571-273-8300**.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

MB

June 14, 2006

JANET L. ANDRES
SUPERVISORY PATENT EXAMINER